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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,430	12/18/2001	Margaret Anne Stanley	5673-61953	6443

7590 03/09/2004
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EXAMINER

LI, BAO Q

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/029,430

Applicant(s)

STANLEY ET AL.

Examiner

Bao Qun Li

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2003.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-32,34-37,39 and 40 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 14-32,34-37,39 and 40 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09,647,486.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 06/18/2002.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

Amendment filed on 12/04/2003 has been acknowledged. Claims 33 and 38 are canceled. New Claims 39-40 are added. Claims 14-32, 34-37 and 39-40 are pending.

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 14-18, 20-22, 24-28, 31 and 34-37 with species of HPV L1 proteins with an N-terminal deletion in Paper No. 12 is acknowledged. The traversal is on the ground(s) that subject matter of Group I-III is clearly overlapping. Applicants' argument has been fully considered; groups I-III are rejoined. Claims 14-32, 34-37 and 39-40 in the scope of HPV L1 protein with an N-terminal deletion is considered.

Sequence requirements

2. This application contains sequence disclosures in page 7, that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.
3. Full compliance with the sequence rules by insertions of sequence identification numbers (SEQ ID NO) for each disclosed sequences is required in response to this Office Action. A complete response to this office action should include both compliance with the sequence rules and a response to the Office Action set forth below. Failure to fully comply with **both** these requirements in the time period set forth in this office action will be held non-responsive.

Specification

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter of "a protein subunit structure" in claim 14. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o).
5. A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. In the instant case, please do the following corrections: (1).

change the “aminoacid” with “amino acid” in both claim and in specification; (2). change the word of “ immunising” into “immunizing”; and (3). change the word of ““recognisable” into “recognizable”.

6. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). In the instant case, the following claimed recitations: “protein subunit”, “ a polypeptide binding domain” and a native conformational epitope” lack a proper antecedent explanations in the specification. Please explain and/or amend claim to a proper recitation in the claims that can be supported by the specification as it was originally filed.

New Matter Objection

7. The amendment of paper No. 12 filed on 12/04/2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure, is as follows: (1). In claim 14, line 1 and 2, the recitation of “ protein subunit” is a new matter. In claim 19, line 2 and in claim 23, lines 3-4, the recitations of “a polypeptide binding domain” are new matters. Because there recitations are not disclosed in the specification as it was originally filed.

8. Applicant is required to cancel the new matter in the reply to this Office Action.

New matter Rejection

9. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the amendment of claim 14 introduces a new matter of “a protein subunit”, and in claim 19, line 2 and in claim 23, lines 3-4, the recitations of “a polypeptide binding domain” are new matters. Because these claims are not disclosed in the specification as it was originally filed. Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
11. Claims 18, 19, 20, 23, 25, 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
12. The claim 18, 25, 28 are vague in that the use of a relative term of "derived". Since the specification does not provide a standard for ascertaining the requisite degree of derivation and the term of "derivation" has many interpretations, one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. Therefore the claim is considered as indefinite.
13. Claims 19 and 23 are vague and indefinite in that the metes and bound of "a polypeptide binding domain" are not defined. The claims are interpreted in light of the specification, however, the specification does not give any definition what the "a polypeptide binding domain" is.
14. Claim 20 is vague and indefinite in that the metes and bounds of "a native conformational epitope" are not defined. The claims are interpreted in light of the specification, however, the specification does not give any definition what the "a native conformational epitope" is.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
16. Claims 25-26, 29, 31, 34, 35, 36, 37 are rejected under 35 U.S.C. 102(b) as anticipated by Crum et al. (Virol. 1990, Vol. 178, pp. 238-246).

17. Crum et al. teach a fusion protein comprising about 73% of HPV-16 E4 and 53% of HPV L1 major coat protein. The E4 protein is attached to the 5' N-terminal of L1 protein and comprises an immuogenic epitope since it is able to induce an E4 antibody. The L1 protein has both N-terminal and C-terminal deletion since it only comprises partial of L1 genome ranging from nucleotide 6151-6793 (See the section of Materials and methods on page 239 and 240, and Fig. 2 on page 241). Therefore, the claims are anticipated by the cited reference.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claims 14-32 and 34-37 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gissmann et al. (U.S. Patent No. 6,228,368 B1).

20. The claimed invention is directed to a virus like particle and a fusion protein made by a papilloma virus coat protein L1 fused with an immunogenic peptide of other non-major coat protein to the N-terminal of the L1 protein. The L1 protein can be made from HPV type 16 to 18 is truncated at its N-terminal with deletion up to 10 or 15 amino acids. The other non-major coat protein peptide can be selected from another HPV antigenic protein, such as E1, E2, E6 and E 7 or a fusion tag of histadine that is convenient for affinitive purification.

21. Regarding to claims 14-18, 20-22, 24-28, 30-32, 34-37, Gissmann et al. teaches a method for making a capsomeric construct of papillomavirus by a fusion protein comprising human papilloma virus type 16 L1 protein fused with a peptide of HPV E7 antigen. The fusion protein is synthesized in Sf9 insect cell and expressed as virus like particle with a capsomeric structure (clo. 13, lines 52-60). The L1 protein can be deleted with one or more amino acid residues from either C-terminus or N-terminus or an internal region (See lines 19-24 on col. 5). The HPV16 E7 antigen peptide is about 50 to 98 amino acids long, which is introduced into the 5' EcoRIV site of the L1 protein (See examples 1 & 2 on cols. 8 to 13). Gissman et al. also discloses that the fusion protein can be made by HPV L1 selected from different serotype of HPV, such as serotype 6, 11, 16 or 18 and another non-major coat protein can be selected from the group consisting of E1, E2, E3, E4 E5, E6 and E7 (see claims 1-5, 9, 12-14). Moreover, Gissmann et al also teaches that administration of said capsomeric construct into an animal can induce specific antibodies to the L1 and E7 (col. 15, lines 5-19), indicating that the said HPV VLP construct comprises a native conformational immunogenic epitope of L1 and E7 protein (See Col. 14-16).
22. Regarding to limitation of claims 19, 23, 29 about the fusion protein contains histadine tag for antibody binding and affinity purification, Gissmann et al teaches that the fusion L1 protein can be expresses with six additional histadine tag attached to the C-terminal of the fusion protein. Therefore, His L1 protein can be easily purified by nickel affinity chromatography (col. 6, lines 39-59).
23. While Gissmann et al. teach the histadine peptide is attached to the C-terminal of the L1 protein rather than to the N-terminal as instant claim drafted, it would have been obvious for a person with ordinary skill in the art to be motivated by the disclosure by Gissmann et al. to adapt the method disclosed by him by using the histadine tag for purification because the utilization of histadine as a tag for purification is well known technique in the art. However, whether the tag is attached to the N-terminal or C-terminal is just a design choice. Therefore, the claimed invention as a whole is prima facie obvious absence unexpected results.

Conclusion

Claims 39 and 40 are free of rejection. However, it is not in condition for allowance because they depend on the rejected claims.


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached at 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li
03/05/2004


JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
3/8/04